Appendixes

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (1)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
Class III products	1. In all circumstances	Products have not been approved by the country	Document of approval for clinical trial in
		of origin for sale in the home market.	China, clinical trial scheme and clinical
			trial report are required.
Class III implantables	2. Enterprises whose products	Domestic products have not been approved for	Document of approval for clinical trial in
	have not been marketed in	sale; overseas products have been approved by	China, clinical trial scheme and clinical
	China	the country of origin for sale in the home market.	trial report are required.
	3. Enterprises whose products	A. Including:	As for domestic products, the relevant
	are already in the Chinese	1. Domestic products have not been approved	clinical report is required;
	market	for sale; overseas products have been	As for overseas products, clinical report
		approved by the country of origin for sale in	issued upon approval by the government
		the home market;	of origin for registration and sale is
		2. The Quality System of the enterprise has been	required. This report still waits to be
		inspected by the Chinese government, but the	approved by the specialist panel selected
		applied product is not manufactured under the	by the Chinese government.
		same QS.	

Ві	including:	As for domestic products, the relevant
		clinical report is required;
1.	Domestic products have not been approved	
	for sale; overseas products have been	As for overseas products, clinical report
	approved by the country of origin for sale in	issued upon approval by the government
	the home market;	origin for registration and sale is
2.	The Quality System of the enterprise has	required.
	been inspected by the Chinese government,	
	and the applied product is manufactured	
	under this QS within its term of validity;	
3.	Other products of the enterprise have been	
	marketed in China with no record of	
	complaint for more than four years.	
No	ote: products with record of complaint shall be	
sub	bject to the implementation of regulation A.	

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (2)

	Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (2)			
Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report	
Class III implantables	4. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of the same series yet not the same model.	 A. Including: Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; The Quality System of the enterprise has been inspected by the Chinese government, but the applied product is not manufactured under the same QS. 	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report of products of the same series issued upon approval for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.	
		 A. Including: Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; The Quality System of the enterprise has been inspected by the Chinese government, and the applied product is manufactured under this QS within its term of validity. Products of the enterprise within the same series have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A. 	As for domestic products, clinical report of products of the same series upon registration and sale is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required	
	5. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of	A. Including:1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report	

the	ne same model yet not the same		the home market;	issued upon approval by the government of
sp	pecifications.	2.	The Quality System of the enterprise has	origin for registration and sale is required.
			been inspected by the Chinese government,	This report still waits to be approved by
			but the applied product is not manufactured	the specialist panel selected by the Chinese
			under the same QS.	government.
		B.	Including:	As for domestic products, clinical report of
				products of the same series upon
		1.	Domestic products have not been approved	registration and sale is required;
			for sale; overseas products have been	
			approved by the country of origin for sale in	As for overseas products, clinical report of
			the home market;	products of the same series issued upon
		2.	The Quality System of the enterprise has	approval by the government of origin for
			been inspected by the Chinese government,	registration and sale is required.
			and the applied product is manufactured	
			under this QS within its term of validity;	
		3.	Products of the enterprise within the same	
			series have been marketed in China with no	
			record of complaint for more than four years.	
		No	te: products with record of complaint shall be	
		sub	eject to the implementation of regulation A.	

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical
Other class III products	6. Enterprises whose products have not been marketed in China	Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market;	Report As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
	7. Enterprises whose products are already in the Chinese market; initial marketing of the applied products in the Chinese market.	 A. Including: Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; Products pertain to therapeutic device using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles. B. Including: Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; Products pertain to either diagnostic device or therapeutic device not using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles. Other products of the enterprise have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A. 	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government. As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required.

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (4)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
products are already in the market. The apparent and the register	8. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of the same series.	 A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. Products pertain to therapeutic device using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles. 	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
		 B. Including: Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; Products of the same series by the enterprise have been marketed in China with no record of complaint for more than four years; Products with record of complaint shall be subject to the implementation of regulation A. 	Clinical report of products of the same series upon approval for registration and sale is required.
Class II products	1. In all circumstances;	Domestic products have not been approved by the Chinese government for sale; overseas products have not been approved by the country of origin for sale in the home market;	Document of approval for clinical trial in China, clinical trial scheme and clinical trial report are required.
	2. Initial marketing of the products in the Chinese market.	A: Overseas products have been approved by the country of origin for sale in the home market.	Clinical report issued upon approval by the government of origin for sale is required.

1	B: Domestic products of the same series have	Clinical report of products of the same
	been approved by the Chinese government for	series upon approval for registration and
	sale in the home market and have been on sale	sale is required.
	for more than two years.	

Notes:

- 2. The term *products of the same series* refers to products sharing the same basic principles, major functions and structure;
- 3. The term *products of the same model* refers to products of the same principle and structure in terms of supplementary functions, while they share the same basic principles, major functions and structure;
- 4. The term *products of the same specifications* refers to products of the same parameters and indexes in terms of major functions, while they share the same basic principles, major functions, structure as well as the same principle and structure in terms of supplementary functions;
- 5. The term *complaint* refers to cases accepted by the drug administrations at state, provincial and municipal levels and decided by technical method to have been caused by problems concerning product quality;
- 5. The term *products* in this chart refers all to edical device